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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/832,355

04/10/2001

Imre Kovessdi

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05/16/2005

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EXAMINER

SPECTOR, LORRAINE

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,355

Applicant(s)

KOVESDI ET AL.

Examiner

Lorraine Spector, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,12,13,16-28,30-41 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 8,13 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9,12,16-19,28,30-41 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,7-9,12,13,16-28,30-41 and 47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2004 has been entered.

Claims 1-5, 7, 9, 12, 16-19, 28, 30-41 and 47 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7, 9, 12, 16-19, 32-34, 39, 40 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Davis et al., WO00/37642 for reasons of record, as affirmed by the Board of Appeals and Interferences in the decision mailed 9/22/2004.

It is noted that claim 1 has been amended to include the limitations of claim 6, which was previously not rejected over Davis et al. However, as a compound and its properties are inseparable, and as Davis fairly teaches the claimed compounds, rejection is proper. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 9, 17, 18, 32-34, 40, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon et al., Life Sciences 64(16):1435-1445, 1997, cited by applicants, in view of either or both of Gill et al., U.S. Patent Number 6,291,667 and Rockwell et al., U.S. Patent Number 5,874,542 for reasons of record, as affirmed by the Board of Appeals and Interferences in the decision mailed 9/22/2004.

It is noted that claim 1 has been amended to include the limitations of claim 6, which was previously not subject to this ground of rejection. However, as a compound and its properties are inseparable, and as Davis fairly teaches the claimed compounds, rejection is proper. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

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Claims 1-5, 7, 9, 12, 16, 18-19, 28, 30-38 40-41 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al., U.S. Patent No. 6,852,323, in view of Bell et al., U.S. Patent No. 4,935,233 and Potter et al., U.S. Patent No. 5,594,107.

Lue et al. teaches the coadministration of BDNF and VEGF, see for example column 11 beginning at line 1, and column 13, beginning at line 63. At column 14, Lue et al. state that it is desirable to make formulations that enhance the functional or structural half-life of VEGF or BDNF. Also at column 14, Lue et al. teach that it is desirable to administer VEGF and BDNF via a gene therapy vector, such as a replication-defective recombinant adenoviral vector, see lines 12-19. The disclosure of Lue et al. differs from the claimed invention in that it does not teach or suggest linking the VEGF to the BDNF in a fusion protein.

The linking together of cytokines in a fusion protein is now old in the art. For example, Bell et al. teach the production of just such proteins which “encompasses mixed function proteins formed from covalently linked polypeptide cell modulators represented as R_1 -L- R_2 , “each of which (R_1 and R_2) acts through a different and specific cell receptor to initiate complementary biological activities”. Specifically included cytokines include “endothelial-derived growth factors” (which would include VEGF), and “neurotrophic growth factors”, which would include BDNF, which is an acronym for “brain derived neurotrophic factor”. Potter et al. is cited as evidence that fusion constructs such as those of Bell et al. gained wide acceptance in the art; at column 2, line 62, Potter et al., state that “Gene fusions provide a convenient method for the production of chimeric proteins. The expression of a chimeric protein... allows the simultaneous delivery of both agents to a desired recipient.”

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Lue et al. by constructing a fusion protein comprising VEGF and BDNF as taught by Bell et al., in view of the teaching by Potter et al. that such fusion proteins are desirable when it is desired to coadminister two proteins. It would further have been obvious to construct a replication deficient adenoviral vector engineered to express the fusion protein, in view of Lue’s teaching that it is desirable to practice Lue’s invention via gene therapy, using just such a vector. Accordingly, the claimed subject matter is *prima facie* obvious.

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Conclusion

No claim is allowed.

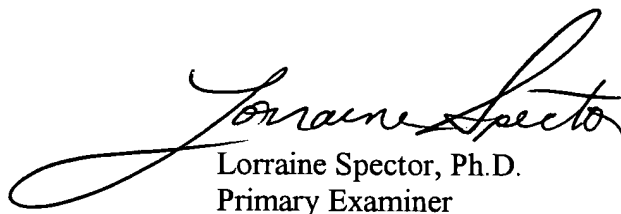
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lorraine Spector, Ph.D.
Primary Examiner